5.0 510(k) Summary – K123591

5.1 General Information:

DEC 2 7 2012

Submitter's Name and Address:	Medtronic CryoCath LP 16771 Chemin Ste-Marie Kirkland, Quebec H9H 5H3, CANADA
Official Correspondent:	Vanessa Ware Principal Regulatory Affairs Specialist Telephone: 763.526.2743 Fax: 763.367.9903 Medtronic CryoCath LP Coral Sea Street Mounds View, MN 55112
Date of Summary:	November 20, 2012-*Revised December 7, 2012*
Trade Name:	FlexCath Advance™ Steerable Sheath & Dilator Steerable Catheter
Common Name:	Steerable Sheath and Dilator
Classification Name:	Steerable Catheter
Classification:	Class II, 21 CFR § 870.1280
Product Code:	DRA
Predicate Device(s):	FlexCath® Steerable Sheath & Dilator, Model 3FC12 (K102176)

5.2 Device Description

The FlexCath Advance Steerable Sheath is a sterile, single use percutaneous introducer fitted with a valve to allow for introduction, withdrawal and swapping of catheters and wires while preventing air ingress and minimizing blood loss. A side-port with stopcock is integrated to allow continuous drip infusion, injection through the center lumen, flushing, aspiration, blood sampling and pressure monitoring.

The FlexCath can be deflected to provide additional maneuverability to catheters that are advance through the sheath and into the right or left chamber of the heart. The FlexCath Advance Steerable Sheath is comprised of two (2) main sections: the shaft and the handle. A dilator is included with each sheath.

This application addresses modifications to the 12 French (12F) FlexCath Steerable Sheath which resulted in the creation of the 12F FlexCath Advance Steerable Sheath (4FC12).

Modifications were made to the stopcock, shaft (pullwire and ring assembly), deflection stopper, and barrel and slider assembly. In addition, an updated Technical Manual (Instructions for Use) and updated packaging labeling was developed for the FlexCath Advance Steerable Sheath.

5.3 Intended Use

The FlexCath Advance Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.

5.3.1 Technological Characteristics Comparison of New Device to Predicate Device

The FlexCath Advance Steerable Sheath and Dilator, with the modified valve assembly (stopcock) and shaft pullwire assembly (both transparent to the user), modified deflection stopper (increased deflection with same reach) and modified barrel and threaded slider, has the following similarities to the predicate device previously cleared under K102176:

- Same Indication For Use
- Same fundamental scientific technology
- Same unidirectional deflection
- Same basic sheath design (dimensions, bullnose tip shape)
- Same user interface with handle (rotating actuator for deflection)
- Same materials
- Same sterilization process

5.4 Summary of Performance Tests

Verification and validation activities were performed to ensure that the FlexCath Advance Steerable Sheath and Dilator fulfilled system requirements and to ensure that the product design conforms to the user needs and intended uses. Performance testing included mechanical testing, shelf-life, and biocompatibility in accordance with applicable industry standards and FDA guidance. Testing included:

- Sheath Valve Assembly (Stopcock) – Leak and Flush Testing
- Sheath Shaft Pull Wire Assembly – Deflection Testing, System Device Compatibility, Interactions, Tensile Strength
- Stopper – Catheter Sheath Kink and Deflection
- Barrel and Threaded Slider – Maintain Deflection, Sheath Shape

Test not repeated and leveraged from predicate because of the same design attributes include:

- Bond pull forces
- Packaging integrity
- Dilator placement, compatibility, visibility under fluoroscopy
- Sheath deflection with a rotating actuator
- Hemostasis valve aspiration flush test and seal with fluid and under pressure
- Sheath shaft visibility under fluoroscopy
- Flushing and aspiration while loaded with catheter

Shelf Life Testing:

Shelf life design verification testing was completed to ensure that device specifications of the product were met after a 12-month accelerated aging study after design modifications to the sheath valve assembly, pullwire assembly, deflection stopper, and barrel and threaded slider. All testing passed. Testing showed that the function and mechanical characteristics of the modified device are not compromised after a 12-month accelerated aging study.

Biocompatibility Testing:

The stopcock (Supplier: Elcam Medical) was assessed for biocompatibility with the guidance from ISO 10993-1 standard or USP Class VI by the supplier. All materials of the stopcock were tested and/or assessed to determine equivalency to a material that was already tested and determined to be biocompatible. The devices or materials were subjected to the following tests:

- Cytotoxicity
- Sensitization
- Skin Irritation or Intracutaneous Reactivity
- Acute systemic toxicity
- Hemolysis
- Optional Tests:
    - Determination of physiochemical Attributes (in purified water) and/or
    - Determination of physiochemical Attributes (in isopropyl alcohol) and/or
    - Pyrogen Study

Leveraged biocompatibility of the predicate device included:

- Kligman Maximization Test per ISO 10993-10 (2002)
- Rabbit Pyrogen Test – Material Meditated per ISO 10993-11 (2006)
- Intracutaneous Test per ISO 10993-10 (2002)
- Systemic Injection Test per ISO 10993-11 (2006)
- Complement Activation Assay per ISO 10993-4 (2002)
- UPTT per ISO 10993-4 (2002)
- Thrombogenicity In vivo canine per ISO 10993-4 (2002)

All test successfully passed. The results if the bench testing demonstrate that the FlexCath Advance Steerable Sheath and Dilator meet the established specifications necessary for consistent performance for its intended use and is substantially equivalent to the predicate (FlexCath Steerable Sheath and Dilator).

5.5 Discussion of Testing Supporting Substantial Equivalence

Non-clinical performance testing (bench testing) was performed to support substantial equivalence between the FlexCath Advance Steerable Sheath (4FC12) and the predicate FlexCath Steerable Sheath and Dilator (3FC12) previous cleared under K102176. All relevant key performance attributes were tested on the FlexCath Advance against performance

requirements, and some test were leveraged from the predicate device and not repeated. The FlexCath Advance does not provide a new therapy and the intended use/indication for use remains equivalent to that of approved FlexCath, Model 3FC12. It was determined that modifications of features to the FlexCath Steerable Sheath had no impact on safety and performance and all testing demonstrated that acceptance criteria were met. In addition, the testing demonstrates that the device does not raise new questions of safety or effectiveness when compared to the predicate.

5.6 Conclusion

Design verification testing was performed to verify that the performance of FlexCath Advance remains substantially equivalent to the predicate device. All test results demonstrate that the properties and performance of the device are suitable for its intended use. There are no differences between devices or in testing which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 7 2012

Medtronic Cryocath Lp
c/o Ms. Vanessa Ware
8200 Coral Sea Street NE MS MVS46
Mounds view, MN 55112

Re: K123591
Trade/Device Name: Flexcath advance steerable sheath (12 french)
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable catheter
Regulatory Class: Class II
Product Code: DRA
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Ware:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 Statement of Indications for Use

510(k) Number (if known): K 123591

Device Name: FlexCath Advance ™ Steerable Sheath and Dilator

Indications for Use:

The FlexCath Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123591